105 CMR 480.000 STORAGE AND DISPOSAL OF INFECTIOUS OR PHYSICALLY DANGEROUS MEDICAL OR BIOLOGICAL WASTE STATE SANITARY CODE CHAPTER VIII

Section

480.001: Purpose

The purpose of 105 CMR 480.000 is to set forth the requirements for the storage and disposal of infectious or physically dangerous medical or biological waste.

480.002: Authority

105 CMR 480.000 is adopted under authority of M.G.L. c. 111, §§ 3, 5 and 127A.

480.003: Citation

105 CMR 480.000 shall be known and may be cited as, 105 CMR 480.000: *Storage and Disposal of Infectious or Physically Dangerous Medical or Biological Waste State Sanitary Code Chapter VII*.

480.004: Scope

105 CMR 480.000 shall apply to all generators of infectious or physically dangerous medical or biological waste except for private residences.

480.010: Definitions

Approved Incineration Facility: A facility approved and classified by the Department of Environmental Protection for incineration of waste; or an out-of-state incinerator approved for incineration of waste by the appropriate regulatory agency.

Board of Health: The appropriate and legally designated health authority of the city, town, or other legally constituted governmental unit within the Commonwealth having the usual powers and duties of the board of health of a city or town or his or its authorized agent or representative.

Department: Department of Public Health

Incinerate/Incineration: The controlled flame combustion of materials in an enclosed system to thermally break down and render the waste noninfectious.

480.010: continued

Infectious or Physically Dangerous Medical or Biological Waste: Waste which because of its characteristics may: cause, or significantly contribute to an increase in mortality or an increase in serious irreversible or incapacitating reversible illness; or pose a substantial present potential hazard to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed.

The following types of waste are identified and defined as infectious or physically dangerous medical or biological waste, and shall be subject to the requirements of 105 CMR 480.000:

(a) Blood and Blood Products: Discarded bulk human blood and blood products in free draining, liquid state; body fluids contaminated with visible blood; and materials saturated/dripping with blood.

(b) Pathological Waste: Human anatomical parts, organs, tissues and body fluids removed and discarded during surgery or autopsy, or other medical procedures and specimens of body fluids and their containers.

(c) Cultures and Stocks of Infectious Agents and Associated Biologicals: All discarded cultures and stocks of infectious agents and associated biologicals, biotechnological by-product effluents, cultures of specimens from medical and pathological laboratories, cultures and stocks of infectious agents from research laboratories, wastes from the production of biologicals, and discarded live and attenuated vaccines intended for human use.

(d) Contaminated Animal Carcasses, Body Parts and Bedding: The contaminated carcasses and body parts and bedding of all research animals known to be exposed to pathogens.

(e) Sharps: Discarded medical articles that may cause puncture or cuts, including but not limited to all used and discarded hypodermic needles and syringes, pasteur pipettes, broken medical glassware, scalpel blades, disposable razors, and suture needles.

(f) Biotechnological By-Product Effluents: Any discarded preparations made from genetically altered living organisms and their products.

Infectious or Physically Dangerous Medical or Biological Waste shall be referred to as "Waste" in the subsequent provisions of 105 CMR 480.000.

Interment: Burial in a cemetery.

Waste Generator (Generator): Any person, corporation, partnership, trust, association, society, organized group of persons, body politic and corporate, public agency, authority, department, office and political subdivision of the commonwealth, who generates waste, provided however that this definition shall not include persons who produce waste in a private residence which is not used to conduct a business. The term "waste generator" includes home health agencies providing services in private residences.

480.020: When Waste is Subject to 105 CMR 480.000

(A) Once material becomes waste, as defined in 105 CMR 480.010, such material shall remain waste and shall be subject to the requirements of 105 CMR 480.000 unless and until it has been both labeled in compliance with 105 CMR 480.300 and disposed of in compliance with 105 CMR 480.200 as applicable.

(B) The requirements of 105 CMR 480.000 shall not apply to waste which is contained in a mixture which, due to the presence of other materials, is subject to regulation as a hazardous or radioactive waste.

480.100 Storage

(A) Waste generators shall contain and store medical waste at all times in leakproof, rodent proof, flytight, containers which ensure that no discharge or release of such waste occurs and that no odor or other nuisance is created.

480.100: continued

(B) All onsite storage of containers of waste shall be held in an area away from general traffic flow patterns, preferably in a room identified for this purpose. The manner of storage shall restrict access or contact with such waste to authorized persons only.

(C) Sharps shall be segregated from other wastes and aggregated in leakproof, rigid, puncture-resistant, shatterproof containers immediately after use.

(D) Wastes other than free draining blood and blood products, sharps and biotechnology by-product effluents shall be placed in a non-permeable three mil or greater polyethylene bag (or equivalent) which is securely sealed to eliminate leaks.

(E) Free draining blood and blood products and biotechnology by-product effluents shall be stored at all times in leakproof containers that are securely sealed.

(F) Compactors or grinders shall not be used to process waste until it has been rendered noninfectious and safe for disposal. The following methods of treatment shall be used as appropriate:

(a) Steam sterilization
(b) Gas sterilization
(c) Chemical disinfection
(d) Incineration at an approved incineration facility
(e) Other methods approved by the Department

480.200 Disposal

(A) Blood and Blood Products

(1) If the waste generator is connected to a municipal sewerage system or septic system, free draining blood and blood products except blood saturated materials may be disposed of directly into these systems unless such disposal is otherwise restricted by the authorized approving agency.

(2) If the waste generator is prohibited by the authorized approving agency from disposing of blood and blood products into the municipal sewerage system or septic system, blood and blood products, except blood saturated materials, shall be sent to an approved incineration facility for incineration or shall be rendered noninfectious by gas, chemical or steam sterilization prior to disposal and disposed of in a sanitary landfill approved by the Department of Environmental Protection or in case of out-of-state disposal, approved by the appropriate regulatory agency responsible for landfill approval.

(B) Sharps. Containers of sharps shall either be:

(1) disposed of by incineration at an approved incineration facility; or

(2) rendered noninfectious as set forth in 105 CMR 480.100(F) and processed by grinding or other effective method to eliminate the physical hazard of the sharps and disposed of in a sanitary landfill approved by the Department of Environmental Protection or in the case of out-of-state disposal, approved by the appropriate regulatory agency responsible for landfill approval.

(C) Blood Saturated Materials, Cultures and Stocks of Infectious Agents and Associated Biologicals, Dialysis Waste and Laboratory Waste. These wastes shall either be:

(1) Rendered noninfectious on site by steam sterilization, incineration, thermal inactivation, or chemical disinfection and disposed of in a sanitary landfill approved by the Department of Environmental Protection or in the case of out-of-state disposal, approved by the appropriate regulatory agency responsible for landfill approval; or

(2) disposed of onsite at an approved incineration facility, or placed in a second 3 mil bag for transport to an approved incineration facility off-site.

480.200: continued

(D) Biotechnology By-Product Effluents

(1) These wastes shall not be removed from the site of the waste generator unless the viable organism containing recombinant DNA molecules have been rendered noninfectious by a validated method.

(2) The following methods shall be used as appropriate:

(a) Steam sterilization

(b) Chemical disinfection

(c) Incineration at an approved incineration facility

(d) Other methods approved by the Department

(3) The methods which rely on heat shall be evaluated mechanically and biologically by using a recording thermometer and indicator microorganism with a defined heat susceptibility pattern.

(4) If these wastes are rendered noninfectious by chemical disinfection, the chemical used shall be of demonstrated efficacy against the target or indicator organism.

(5) Once rendered noninfectious, biotechnology by-product effluents may be disposed of directly into the waste generator's connection to the municipal sewerage system or septic system unless such disposal is otherwise restricted by the authorized approving agency.

(6) If the generator is prohibited by the authorized approving agency from disposing of biotechnology by-product effluents through the municipal sewerage system or septic system, these wastes shall be rendered noninfectious and disposed of in a sanitary landfill approved by the Department of Environmental Protection or in the case of out-of-state disposal, approved by the appropriate regulatory agency responsible for landfill approval.

(E) Pathological waste and contaminated animal carcasses shall be disposed of at an approved incineration facility or by interment provided however that liquid pathological waste may also be disposed in accordance with 105 CMR 480.200(A) and discarded teeth and tissue may also be disposed of in accordance with 105 CMR 480.200(C)(1). These wastes shall be placed in a second three mil bag if they are to be transported off-site for disposal.

480.300: Labeling

(A) Every container or bag of waste which has not been rendered noninfectious shall:

(1) be distinctively marked with the international biohazard symbol and colored red to indicate that it contains waste; and

(2) in the case of sharp wastes, be distinctively labeled to indicate that it contains sharp waste capable of inflicting punctures or cuts.

(B) Every container or bag of waste which has not been rendered noninfectious and which will be transported off the premises of the waste generator shall in addition to the requirements of 105 CMR 480.300(A):

(1) be placed in containers which are:

(a) rigid

(b) leak resistant

(c) impervious to moisture

(d) of sufficient strength to prevent tearing or bursting under normal conditions of use and handling, and

(e) sealed to prevent leakage during transport.

(2) bear a label which states the name, address and telephone number of the generator. The label shall be affixed in a manner which ensures that it cannot be easily removed.

(C) Prior to transport for off-site disposal, waste which has been rendered noninfectious by a method other than incineration shall be labeled or otherwise marked so as to clearly identify it as noninfectious medical or biological waste and to identify the waste generator responsible for the treatment. Such waste may be disposed of in the same manner as waste which is not regulated by 105 CMR 480.000, except for sharps, which shall be disposed of in accordance with the requirements of 105 CMR 480.200(B).

480.400: Policies and Procedures; Records

(A) Written policies and procedures for rendering waste noninfectious shall be developed that assure effectiveness and compliance with the requirements set forth in 105 CMR 480.000.

(B) The waste generator shall maintain records of temperature and dwell times used in each instance where waste has been rendered noninfectious by gas or steam sterilization and records of each biological spore test culture result. Such records shall be retained for at least three years.

(C) The waste generator shall maintain records of volume and type of waste rendered noninfectious on-site which shall be available for Department review. Such records shall be retained for at least three years.

480.500: Manifests

(A) Generators shall prepare manifests before shipping waste which has not been rendered noninfectious off-site. The manifest is a tracking document designed to record the movement of waste from the generator through its trip with a transporter to an approved disposal facility and final disposal. The generator shall appoint a designee to prepare, sign and maintain such manifests.

(B) The manifest must include the following information:
(1) description of waste to be shipped;
(2) total quantity of waste; and
(3) type of container in which waste is transported.

(C) A generator shall designate on the manifest the address of the site to which the waste is to be delivered and sign it. The transporter of the waste or an agent of the transporter shall sign the manifest to indicate that the transporter has received the waste and will comply with the generator's transportation instructions. When the waste arrives at the approved off-site disposal facility, and has been disposed of, the disposal facility owner or agent of the owner shall sign the manifest and return the original to the generator.

(D) If the generator does not receive the manifest from the disposal facility within 30 days after shipment of waste by the generator, the generator shall report this fact to the Department of Public Health.

(E) The generator shall maintain a copy of the manifest both as initially sent out and as returned by the disposal facility for a period of three years.

(F) In the absence of any restriction concerning individuals who are authorized to transport waste, including but not limited to those imposed by boards of health or the Department of Environmental Protection, generators who transport their own waste shall follow the manifest requirements set forth in 105 CMR 480.500.

480.550: Approval of Additional Methods of Treatment, Storage and Disposal

Notwithstanding the requirements of the previous sections, the Department may approve additional methods for the treatment, storage or disposal of infectious or physically dangerous medical or biological waste under the following conditions:

(A) the method has been validated through scientific studies acceptable to the Department, and

(B) if the waste is to be transported off-site, the waste treatment facility has been approved by the Department of Environmental Protection, or

(C) if the waste is to be transported out-of-state, the waste treatment facility has been approved by the appropriate regulatory agency in that state.

480.600: Administration and Enforcement

(A) Scope. The following provisions shall cover the administration and enforcement of 105 CMR 480.000 in lieu of 105 CMR 400.000: *The State Sanitary Code, Chapter I: General Provisions*.

(B) Inspection Authority. In order to properly carry out their respective responsibilities under 105 CMR 480.000 and to properly protect the health and well-being of the people of the Commonwealth, the Department, in the case of generators which are health care facilities licensed by the Department, and the boards of health and the Department, in the case of all other generators, or the authorized agent or representative of either are authorized to enter, examine, or survey at any reasonable time such places as they consider necessary, and otherwise to conduct such examination or survey as is required to carry out the provisions of 105 CMR 480.000.

(C) Notices. If as a result of any inspection the board of health or the Department finds a violation of 105 CMR 480.000, the board of health or the Department shall issue a notice to the waste generator which sets forth the nature of the violation and warns said generator that a second such violation may result in legal action. However, the board of health and the Department shall have the authority to initiate proceedings to enforce 105 CMR 480.000 without prior notice in those circumstances in which the board of health or Department determines that immediate proceedings are warranted.

(D) Penalty. Any person who violates any provision of 105 CMR 480.000 other than 105 CMR 480.200 shall, upon conviction, be fined not less than $100 nor more than $500 per day of violation. The penalty for violation of any provision of 105 CMR 480.200 shall, upon conviction, be a fine of not more than $25,000 or up to two years in a house of correction.

(E) Injunctions. The Department may seek to enjoin violations of 105 CMR 480.000 pursuant but not limited to M.G.L. c. 127A and to M.G.L. c. 214, § 3(12). Boards of health may seek to enjoin such violations in accordance with applicable law, including but not limited to M.G.L. c. 127A.

(F) Variance.

(1) The boards of health may vary the application of any provision of 105 CMR 480.000 with respect to any particular case when, in its opinion, the enforcement thereof would do manifest injustice; provided that the decision of the board of health shall not conflict with the spirit of any minimum standard established by 105 CMR 480.000. No such variance shall be effective until it has also been approved by the Department. If the Department does not disapprove the variance within 30 days of receipt it shall be deemed to be approved. Any variance granted by a board of health shall be in writing. A copy of any such variance shall, while it is in effect, be available to the public at all reasonable hours in the office of the board of health.

(2) Any variance or other modification authorized to be made by 105 CMR 480.000 may be subject to such qualification, revocation, suspension, or expiration as the board of health expresses in its grant. A variance or other modification authorized to be made by 105 CMR 480.000 may otherwise be revoked, modified, or suspended, in whole or in part, only after the holder thereof has been notified in writing and has been given an opportunity to be heard.

(G) Removal of Nuisance by Board of Health. Pursuant to the provisions of M.G.L. c. 111, §§ 122 through 125, a board of health may also act to abate any nuisance which is caused by a failure to comply with the provisions of 105 CMR 480.000 thereby endangering or materially impairing the health and safety and well-being of the public, and to charge the responsible person or persons with any and all expenses incurred.

(H) Notice Concerning Violations by Registered Professionals. If the Department or local board of health issues a notice pursuant to 105 CMR 480.600(C) or obtains a conviction and/or fine pursuant to 105 CMR 480.600(D) with respect to a registered professional, the Department or local board of health shall notify the appropriate professional registration board.

480.700: Severability

If any section, paragraph, sentence, clause, phrase or word of 105 CMR 480.000 shall be declared invalid for any reason whatsoever, that decision shall not affect any other portion of 105 CMR 480.000, which shall remain in full force and effect; and to this end the provisions of 105 CMR 480.000 are hereby declared severable.

REGULATORY AUTHORITY

105 CMR 480.000: M.G.L. c. 111, §§ 3 and 5; c. 127A.

NON-TEXT PAGE